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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,987	01/21/2004	Scott L. Childs	14245US02	9485
<div>7590 02/07/2007</div> <div>Michael B. Harlin McAndrews, Held & Malloy, Ltd. 34th Floor 500 West Madison Street Chicago, IL 60661</div>			<div>EXAMINER</div> <div>VALENROD, YEVGENY</div>	
			<div>ART UNIT</div> <div>1621</div>	<div>PAPER NUMBER</div>
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/07/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/763,987

Applicant(s)

CHILDS, SCOTT L.

Examiner

Yevgeny Valenrod

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) 1-57 and 61-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/23/04; 10/20/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III, claims 58-60 in the reply filed on 11/14/06 is acknowledged. The traversal is on the ground(s) that the search of groups III, VI and VII together does not constitute an undue burden on the office. This is not found persuasive because the search of group III does not require a search hydrate or solvate starting material, limitations of the independent claims 65 and 67.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-57 and 61-99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/14/06.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. The term "coordinate more strongly" in claims 58-60 is a relative term which renders the claim indefinite. The term "more strongly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specification does not provide one of ordinary skill in the art with a method of

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determining the relative strengths of coordination of the quest with the counterion or of the strength of coordination within a crystal.

3. Claims 58-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are directed to crystals, where salt of active agents and quests are the components of the said crystal. It is not clear to one of ordinary skill in the art what the term "active agent" and "guest" encompass. On page 14 of the specification applicant defines "active agent" as "...the molecule whose activity is desirable or the object of interest". On page 19 the term "Guest" is discussed, however no clear definition of the said term appears in the specification. It is not clear which structures are included and which ones are excluded by the above terminology.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 58-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way to convey reasonably to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The issue concerning the meaning of terms "active agent" and "guest" are discussed above. Claims 58-60 do not contain a complete generic formula for either of the said terms.

According to the MPEP §2163 I. A. "the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art." The MPEP states in §2163 II 3 ii) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406." Applicants have disclosed no species and no generic structure of the "active agent" or "guest"

The Court of Appeals for the Federal Circuit held in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 at 1406. "[a] written description of an invention involving

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a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name, "of the claimed subject matter sufficient to distinguish it from other materials. *In re Smythe*, 480 F.2d 1376, 1383, *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .")." Applicants' functional definitions in the claimed method simply lack the precision required by the Court of Appeals for the Federal Circuit.

5. Claims 58-60 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making cocrystals of fluxetineHCl : fumaric acid, fluxetineHCl : benzoic acid and fluxetineHCl :succinic acid, does not reasonably provide enablement for a method of forming cocrystals of other active agent salts and guests. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The how to make requirement of the enablement statute, when applied to process claims, refers to operability and how to make the claimed process work. "The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance

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presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims", In re Rainer, 146 USPQ 218 (1965); In re Colianni, 195 USPQ 150, Ex parte Formal, 230 USPQ 546.

The quantity of experimentation required in order to practice the invention with any active agent salt and any guest is quite great. For each active agent salt – guest combination one of skill in the art would have to perform numerous experiments that include determining 1) the best solvent / combination of solvents to use, 2) the correct amount of the solvent or proportions of the solvent / co-solvent, or in the case of a physical mixture or a melt the amounts of ingredients, 3) a method by which theorizing the coordination by hydrogen bonding would be done, 4) a method of ascertaining the relative strength of the interactions within a crystal and between counterion and the guest.

The amount of direction presented by the applicant amounts to suggestion of what can be done using his method of crystallization. There are no clear steps described in the specification that one of ordinary skill in the art might utilize in practicing the invention. Specification adequately describes possible uses of the invention, however only limited examples are present which provide enablement for a very limited number of agent salt – guest combination.

Working examples are limited to crystallization of FluxetineHCl salt with one of three carboxylic acids: benzoic acid, fumaric acid and succinic acid.

The nature of invention is concerning cocrystallization. The method involves forming co-crystals of a salt of an active agent and a guest entity.

The state of prior art and predictability/unpredictability of the art is best summarized by Gavezzotti (*Acc. Chem. Res.* **1994**, 27, 309-314). On page 309, column, 1 first paragraph, Gavezzotti clearly states that crystal structures are unpredictable. On page 9 of the specification applicant states: "The formation of cocrystals is very unpredictable. It is difficult to foresee structural changes as a function of changes in molecular substitution patterns or molecular geometry."

Since the art itself is unpredictable, the relative skill of those in the art is non-existent.

The claims are very broad. There are no structural limitations on either the salt of an active agent or the guest other than the ability to form hydrogen bonds. This definition includes limitless number of molecules.

MPEP §2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58-60 rejected under 35 U.S.C. 102(b) as being anticipated by Homeyer et al. (US 2,665,277 ('277)).

The instant claims are directed to a method of forming a co-crystal. The steps involved are: a) Selecting a salt of an active agent, b) theorizing coordination, c) selecting a guest, d) preparing a solution, e) performing crystallization and f) forming a cocrystal.

Of the above steps, "theorizing coordination" is not given any patentable weight. The said step is purely mental with no physical consequences.

Homeyer et al. describe a method of making morphine phosphate hemihydrate. The said crystal is contains a salt of an active agent (morphine phosphate) and a guest (water). The method (column 2 line 50 – column 3, line 7) described in '277 involves: selecting a salt of an active agent (morphine phosphate), selecting a guest (water), preparing a solution (morphine phosphate is mixed with water), performing crystallization (the mixture is cooled), forming a crystal (column 3, lines 6-7).

Conclusion

Claims 1-99 are pending

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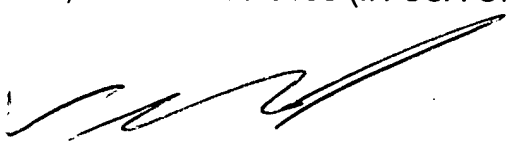
Claims 1-57 and 61-99 are withdrawn

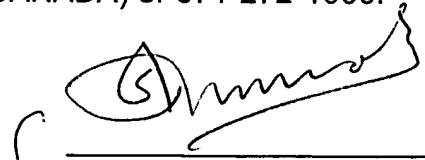
Claims 58-60 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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